

Food and Drug Administration, HHS

§ 520.1720b

drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 58775, Nov. 15, 1994]

§ 520.1720 Phenylbutazone oral dosage forms.

§ 520.1720a Phenylbutazone tablets and boluses.

(a) *Specifications.* Each tablet contains 100, 200, or 400 milligrams, or 1 gram of phenylbutazone. Each bolus contains 2 or 4 grams of phenylbutazone.

(b) *Sponsor.* See sponsor numbers in § 510.600(c) of this chapter, as follows:

(1) No. 000061 for use of 100- or 400-milligram or 1-gram tablets, or 2- or 4-gram boluses, in dogs and horses.

(2) Nos. 000010 and 059130 for use of 100- or 200- milligrams or 1-gram tablets in dogs and horses.

(3) Nos. 000856, 058829 and 061623 for use of 100-milligram or 1-gram tablets in dogs and horses.

(4) No. 055246 for use of 100-milligram tablets in dogs.

(5) No. 000143 for use of 1-gram tablets in horses.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Twenty milligrams per pound of body weight daily.¹

(ii) *Indications for use.* The drug is used for the relief of inflammatory conditions associated with a musculoskeletal system.¹

(iii) *Limitations.* Administer in three divided doses daily. Do not exceed a total daily dose of 800 milligrams regardless of body weight. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at a level capable of producing the desired clinical response. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

(2) *Horses*—(i) *Amount.* One to two grams per 500 pounds weight daily.¹

(ii) *Indications for use.* This drug is used for the relief of inflammatory conditions associated with the musculoskeletal system.¹

(iii) *Limitations.* Do not exceed a daily dosage of 4 grams per day. Administer at a relatively high dosage level for the first 48 hours and then reduce gradu-

ally to a maintenance dosage level with the lowest dosage maintained at the level capable of producing the desired clinical response. Not for use in animals intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[42 FR 44227, Sept. 2, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.1720a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 520.1720b Phenylbutazone granules.

(a) *Specifications.* The drug is in granular form. It is packaged to contain either 8 grams of phenylbutazone per package or 1 gram of phenylbutazone per package.

(b) *Sponsor.* See 000061 in § 510.600(c) for 8-gram package, see 059320 for 1-gram package.

(c) *NAS/NRC status.* The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1 to 2 grams per 500 pounds of body weight, not to exceed 4 grams, daily, as required.

(ii) *Indications.* For the treatment of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations.* Administer orally by adding to a portion of the usual grain ration. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Treated animals should not be slaughtered for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18960, Mar. 27, 1981, as amended at 46 FR 48642, Oct. 2, 1981; 57 FR 2836, Jan. 24, 1992; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 65 FR 20731, Apr. 18, 2000]

¹See footnote 1 to § 520.1660b.